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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,152	07/30/2001	Desmond John Best	PC10947A	2963

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BERCH, MARK L

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1624

DATE MAILED: 05/31/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/918,152	BEST ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/01696 or Elliott.

Compound IIB is disclosed at Example 11, page 59, lines 6-7, and hence anticipates claim 21. In Elliott, see compound 12.

Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/01696 or WO 93/25551 or WO 96/17847.

Compound III is shown as the final product of Example 11 of WO 92/01696 and other examples, albeit made by a different process, and hence claims 20 and 21 anticipated. Likewise WO 96/17847. WO 93/25551 has a similar disclosure for carbacephems. A rejection is proper over a prior art reference which shows the same product, even if made by a different process. See: *In re Thorpe*, 227 USPQ 964; *In re Hirao*, 190 USPQ 15 (see footnote 3); *Ex parte Edwards*, 231 USPQ 981; *In re Pilkington*, 162 USPQ 145, 147; *In re Dilnot*, 133 USPQ 289.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "acyl" is indefinite. Does this embrace acids of S? P? As? What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R? In carboxylic acid acyls, does the carbon count include the carbon of the carbonyl?
2. What does "easily removable" mean? Where is the line between protecting groups which are easily removable and those which are not?
3. The phrasing of "which includes the step of cyclizing" is unclear. Does the process as claimed cover steps prior to the cyclizing, or is the cyclizing the first step? Is there something after the cyclizing, or is that the last step?
4. At page 23, line 14, presumably "R₄alkyl" should be "R₄ = alkyl".
5. "Converting" is indefinite and unduly functional. It simply identifies what is the starting material and what is the final product, without reciting an actual specific step which is performed. (Claim 11 and 18)
6. Claim 12 is garbled. It says that there is configuration VIIIA, but then both VIIIA and VIIIB is given. Should there be an "or" before VIIIB, or should VIIIB be removed? The "or" choice does not make sense --- what else could it be other than A or B?

7. The dependence of claim 15 on claim 11 makes no sense. Claim 11 has no desired configuration.
8. The use of "pinacol" in claim 17 is in error. It cannot be formed from the variable choices listed later in the claim. Further, it makes claim 17 improperly dependent on claim 16. Pinacol would require two of the R variables to be combined, which is not provided for in the definitions provided in claim 16.
9. The limitations of claim 19 are unclear.
10. Claim 21 must set forth what these compounds actually are.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most substituents , does not reasonably provide enablement for $R_4 = Cl$ or OH , or R_4 is alkyl substituted by Cl or OH . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The cyclizing process obviously involves displacement of the leaving group, so that these choices where R_4 is, or has, a leaving group are not enabled. This problem is clearly exacerbated in claims such as 14.

Claims 1-21 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The molecule is depicted in claim as having a minus charge but no plus charge. Specifically, the carboxylate anion can be present for R^3 , but there is no cation present

in the molecule, giving the molecule a net charge of -1. A molecule without electrical neutrality is impossible to prepare and hence lacks enablement in terms of how to make, as such a thing cannot be made (paragraph 1). Note MPEP 2172.01: “A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements ...”. Here, the missing cation is the missing element. On the other hand, if it was not the intention of applicants to claim such a non-neutral molecule, then the claim fails to set forth what applicants intend as their invention (paragraph 2). That is, it is not accurate because it is missing something. As stated in *In re Zletz*, 13 USPQ2d 1320, 1322, “An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous.”

Claim Objections

Claims 4-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiply dependent claim. See MPEP § 608.01(n). Further, claims such as claim 8 fail to specify specifically which claims they depend on. Claim 11 also fails to depend solely in the alternative on other claims.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. Claim 2 embraces the salt, which is not provided for in claim 1.

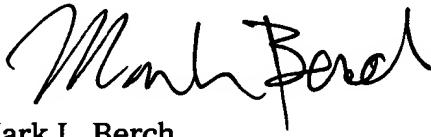
Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

May 31, 2002